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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,312	03/12/2004	Roger Morris	30862.CIP	8203
39313 7590 09/20/2007 CARL M. NAPOLITANO, PH.D. ALLEN, DYER, DOPPELT, MILBRATH & GILCHRIST, P.A. 255 SOUTH ORANGE AVE., SUITE 1401 P.O. BOX 3791 ORLANDO, FL 32802-3791				
			EXAMINER BEISNER, WILLIAM H	
			ART UNIT 1744	.PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,312	<b>Applicant(s)</b> MORRIS ET AL.	
	<b>Examiner</b> William H. Beisner	<b>Art Unit</b> 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) 1-31, 52-56 and 68-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-51 and 57-65 is/are rejected.
- 7) ☒ Claim(s) 66 and 67 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/30/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II, Claims 32-51 and 57-67, in the reply filed on 7/2/2007 is acknowledged.
2. Claims 1-31, 52-56 and 68-99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/2/2007.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 7/30/2004 has been considered and made of record.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 42 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 42 and 50, "the container" lacks antecedent basis. Note both claims 42 and 50 depend from claim 32 which is silent with respect to "a container". It appears that these claims should depend from claim 33.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 57-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al.(US 2002/0044891).

With respect to claim 57, the reference of Miller et al. discloses a sensor that is capable of detecting the presence of bacteria in a perishable food product that includes a gas-permeable material (22) having at least two opposing surfaces exposed to gas diffusion (See especially Figure 4). The gas permeable material includes a pH indicator (See paragraph [0033]).

With respect to claim 58, the sensor is used within a food packaging material or container (See paragraph [0024]).

With respect to claims 59-62, the device can be constructed to detect acidic or alkaline gases (See paragraphs [0026]-[0029]).

With respect to claim 63, the reference discloses the use of edible pH indicators (See paragraph [0030]).

8. Claim 32, 36-39, 43, 44, 46, 57, 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Lampotang et al.(US 4,928,687).

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With respect to claims 32 and 57, the reference of Lampotang et al. discloses a sensor that is capable of detecting the presence of bacteria in a food product. The sensor includes a housing (2) having a bore extending fully therethrough (See Figure 2). A gas-permeable material (L3, 4 and 6) is carried within the bore so as to expose at least two opposing surfaces (See Figure 2). A pH indicator is carried by the gas-permeable material for detecting a change in pH (See column 8, lines 30-41).

With respect to claims 36, 37, 61 and 62, the sensor is responsive to carbon dioxide.

With respect to claims 38 and 39, the sensor changes color (See column 7, line 66, to column 8, line 3).

With respect to claims 43, 44 and 46, the sensor includes gas permeable silicone and an aqueous pH indicator (See column 8, lines 15-41).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al.(US 2002/0044891) in view of Azar et al.(US 2001/0012636).

The reference of Miller et al. has been discussed above.

While the reference of Miller et al. suggests using an edible indicator, the reference is silent as to the source of the edible indicator other than to say it can be used as a food additive (See paragraph [0030]).

The reference of Azar et al. discloses that it is known in the art to employ a pH indicator that is extracted from red cabbage (See paragraph [0083]).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the red cabbage extract of the reference of Azar et al. in the system of the primary reference of Miller et al. for the known and expected results of providing an art recognized non-toxic pH indicator, as is required of the primary reference.

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13. Claims 32, 33, 36-39, 42 and 47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freadman et al. (US 6,589,761) in view of Lampotang et al. (US 4,928,687).

With respect to claim 32, the reference of Freadman et al. discloses a device for detecting a presence of bacteria in a perishable food product that includes a gas-permeable sensor housing (16) and a pH indicator (14) within the housing for detecting a pH change which is indicative of the presence of bacteria. The indicator is carried within a gas-permeable matrix (See column 3, lines 27-64). The pH indicator (14) being safe for human consumption (See column 3, line 44, to column 11, line 13).

Claim 32 differs by reciting that the matrix is held within a housing with a bore extending therethrough.

The reference of Lampotang et al. discloses that it is conventional in the art to provide a pH indicator within a holder or housing that has one surface exposed (See Figure 1) or two exposed surfaces (See Figure 2).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the sensing matrix within a housing with two exposed surfaces as suggested by the reference of Lampotang et al. for the known and expected result of increasing the surface area for contact with the sample space of the housing.

With respect to claim 33, the housing (16) is affixable to the food package interior (12) by mechanical or chemical means (See column 3, lines 9-16).

With respect to claims 36 and 37, the sensor is responsive to carbon dioxide.

With respect to claim 38, the indicator can exhibit a radiative change (See column 4, lines 9-19).

With respect to claim 39, the indicators listed in the reference include indicator compositions that change color commensurate with pH change.

With respect to claims 42 and 50, the housing is capable of being positioned in the manner recited in the claim (See column 3, lines 9-16).

With respect to claim 47, the reference discloses the use of agar (See column 3, lines 46-54).

With respect to claims 48 and 49, the reference disclose any number and/or combination of indicators that can be used (See columns 4-8).

With respect to claim 51, the indicator can be an irreversible change (See column 4, line 16).

14. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freadman et al.(US 6,589,761) in view of Lampotang et al. (US 4,928,687) taken further in view of Shurben (US 4,960,565).

The combination of the references of Freadman et al. and Lampotang et al. has been discussed above.

Claim 40 differs by reciting that the device includes a reference element.

The reference of Shurben discloses that the use of color references with respect to optical detection elements is known in the art (See the abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the device of the primary reference with a reference color for the known and expected



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result of providing a means recognized in the art for allowing the user to verify the color change of the test device.

15. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freadman et al.(US 6,589,761) in view of Lampotang et al. (US 4,928,687) and Shurben (US 4,960,565) taken further in view of Perlman et al.(US 4,526,752).

The combination of the references of Freadman et al., Lampotang et al. and Shurben have been discussed above.

Claim 41 differs by reciting that the color changing element of the device provides a warning icon.

The reference of Perlman et al. discloses that it is known in the art to provide a test element (13) as a warning icon (See Figure 2). The reagent composition is used with reference background on element (13).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide a warning icon in the device of the modified primary reference for the known and expected result of confirming a positive result to the user of the device.

16. Claims 43-46 rejected under 35 U.S.C. 103(a) as being unpatentable over Freadman et al.(US 6,589,761) in view of Lampotang et al. (US 4,928,687) taken further in view of Wolfbeis et al.(US 5,407,829).

The combination of the references of Freadman et al. and Lampotang et al. has been discussed above.

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Claims 43-46 differ by reciting that the pH indicator is encapsulated with silicone.

The reference of Wolfbeis et al. discloses that it is conventional in the art to encapsulate an indicator composition within a silicone material (See Figure 2 and Example 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to encapsulate the pH indicator of the primary reference with silicone for the known and expected result of providing a means recognized in the art for isolating a pH composition within a housing to be used within a food package.

17. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freadman et al.(US 6,589,761) in view of Lampotang et al. (US 4,928,687) taken further in view of Miller et al.(US 2002/0044891).

The combination of the references of Freadman et al. and Lampotang et al. has been discussed above.

Claims 34 and 35 differ by reciting that the sensor is responsive to ammonia in the food container.

The reference of Miller et al. discloses that it is conventional to employ chemical compounds in a sensor that is responsive to a number of items associated with food spoilage, including ammonia (See paragraphs [0026-0029]).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ any chemical known for indicating food spoilage while maintaining the function of the device for detecting spoilage of a food product.

### ***Double Patenting***

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 32-51 and 57-65 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/659,222 in view of Lampotang et al. (US 4,928,687).

Claims 1-16 of Application 10/659,222 encompass a sensing device that is substantially the same as that of instant claims 32-51 and 57-65.

Claims 32-51 and 57-65 differ by reciting that the matrix is held within a housing with a bore extending therethrough.

The reference of Lampotang et al. discloses that it is conventional in the art to provide a pH indicator within a holder or housing that has one surface exposed (See Figure 1) or two exposed surfaces (See Figure 2).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the sensing matrix within a housing with two exposed surfaces as suggested by the reference of Lampotang et al. for the known and expected result of increasing the surface area for contact with the sample space of the housing.

This is a provisional obviousness-type double patenting rejection.

#### ***Allowable Subject Matter***

20. Claims 66 and 67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 66 and 67, the prior art of record fails to teach or fairly suggest mixing the food extract with glucose or sucrose so as to reduce the rate of oxidation and breakdown of the indicator extract.

#### ***Conclusion***

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner  
Art Unit 1744

WHB